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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,306

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Lawrence Solomon

ABT-034

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64546

7590

09/27/2010

ACCU-BREAK TECHNOLOGIES, INC.  
1000 SOUTH PINE ISLAND ROAD  
SUITE 230  
PLANTATION, FL 33324

EXAMINER

BARHAM, BETHANY P

ART UNIT

PAPER NUMBER

1615

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,306	<b>Applicant(s)</b> SOLOMON ET AL.	
	<b>Examiner</b> BETHANY BARHAM	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2010 and 20 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8-22,24 and 27-43 is/are pending in the application.
- 4a) Of the above claim(s) 6,11-14,24 and 27-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8-10,15-22 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicant's Response and Claim amendments filed on 05/11/10 and 08/20/10 is also acknowledged. Claims 1-2, 4-6, 8-22, 24, 27-43 are pending and claims 6, 11-14, 24, and 27-42 remain withdrawn. Claims 1, 2, 4, 5, 8-10, 15-22 and 43 are rejected.

It is noted that the species election of 10/31/09 is still maintained and Applicant elected "(a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio)."

## **MAINTAINED REJECTIONS**

### **DOUBLE PATENTING**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-5, 8-10, 15-22, and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7,329,418. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

Claims 1-2, 4-5, 8-10, 15-22, and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 19 of copending application 10/598267. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

**NEW:**

Claims 1-2, 4-5, 8-10, 15-22, and 43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-17 and 23 of copending application 11/569343. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an immediate release pharmaceutical tablet with at least two or more active segments and at least one inactive segment, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

### ***Response to Arguments***

The ODP rejections are maintained as the Terminal disclaimer of US 7,329,418 filed on 05/11/10 is not proper. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c). The person who signed the terminal disclaimer does not have Power of Attorney. Further, the ODP over 10/598267 is maintained as the copending applications contain overlapping subject matter although the Examiner acknowledges Applicant's agreement to file a TD upon allowable subject matter. Further, due to Applicant's claim amendments an additional ODP over 11/569343 is now made.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1-2, 8-9, 15-17 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0234608 ('608).

The instant claims are drawn to an immediate release pharmaceutical tablet with at least two segments, said tablet containing a drug or drugs, in which: (a) said tablet includes two or more segments wherein at least one segment comprises an inactive composition and all segments that contain a pharmacologically effective dose of a drug or drug contain the same drug (or combination of drugs at the same ratio).

- '608 teaches a composition/tablet containing multiple layers: an expanding layer and an active ingredient layer (i.e. meeting the limitation of "2 or more segments wherein at least one segment comprises an inactive and all segments that contain a ...drug contain the same drug") (abstract, claims 22, 32-36, 54, 66-67, 72 and 75-76; [0072-0075, 0078, 0082]). According to '608 the compositions are for immediate release ([0029, 0033, 0082], claims 54 and 59) (according to the limitations of claim 1).

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- '608 further teaches one or more reservoirs of the same drug, Example 9 teaches a tablet on either side of the expanding layer and an immediate release of methylphenidate is taught and further claims 2 reservoirs tablets of the same active can be compressed with the expanding layer to form the multilayer composition ([0078, 0078, 0185, 0187-0191]; claims 67, 72, 75-77) (according to the limitations of claims 2, 8-9 and 15-17).
- Various drugs are taught for the multilayered tablet of '608 with are known to treat pain, thyroid, etc [0088] (according to the limitations of claim 43).

Claim 1-2, 4-5, 8-10, 17, 19-20, 22 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/18447 ('447).

- '447 teaches a multiplex drug delivery system containing two distinct drug dosage packages with equivalent dissolution profiles and/or identical composition for the active provided in an effective amount that is scored and that the drug dosage packages are immediate release form (abstract, pg. 1 lines 8-10; pg. 3, lines 1-5; Fig. 1) (meeting the limitations of claim 1-2, 5, 8-10, 17, 19-20 and 22).
- According to '447 the immediate release compartment is 3/16 diameter round whereas the scored compartment is 5/16x3/4 (pg. 9, Example) (according to the limitations of claim 4).
- Various drugs are taught for the tablet of '447 with are known to treat arthritis, pain, cardiac diseases, etc (pg. 7, lines 5-pg. 8, lines 20) (according to the limitations of claim 43).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-5, 8-10, 15-17, 19-20, 22, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0234608 ('608) in view of WO 00/18447 ('447).

- '608 is taught above and teach a multilayered drug dosage form with an expanding pharmaceutical free layer (abstracts, claims, etc see above) (according to the limitations of instant claim 1-2, 8-9, 15-17, and 43).
- '608 does not that the tablet is scored or marked or that the height of the first layer and third layer is less than the second.
- '447 is taught above and teaches a tablet of one or more drugs for immediate release, wherein the immediate release (active) compartment is 3/16 diameter round whereas the scored (inactive) compartment is 5/16x3/4 (pg. 9, Example) (according to the limitations of claim 4-5, 19-20 and 22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '608 with '447. A skilled artisan desiring to make the known product (ie multilayered tablet) of '608 ready for improvement, with the known technique of formulating a product an intermediate or second segment which is greater in height

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and contains a mark/score/indicia of '447 for how to formulate such a segment with predictable results. The combination of a known product '608 ready for improvement with a known technique '447 is within the purview of the skilled artisan and would yield predictable results.

Claims 1-2, 5, 8-10, 15-22, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2004/0234608 ('608) in view of WO 00/18447 ('447), US 5,118,021 ('021) and US 4,905,589 ('589).

- '608 is taught above and teach a multilayered drug dosage form with an expanding pharmaceutical free layer (abstracts, claims, etc see above) (according to the limitations of instant claim 1-2, 8-9, 15-17, and 43).
- '608 does not that the tablet is scored or marked or that the height of the first layer and third layer is less than the second.
- '021 discloses that dosage forms, such as tablets, can be marked or scored for splitting and that reasons for reasons for splitting tablets include difficulty of swallowing tablets in whole form and dosage in standard tablet is greater than required (column 1, lines 11-44).
- '589 discloses that an ink-jet apparatus for marking tablets with appropriate indicia (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '608 with '021 or '589. A skilled artisan desiring to make the known product (ie multilayered tablet) of '608 ready for improvement, with the known

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technique of formulating a product which contains a mark/score/indicia of '021 and '589 with predictable results. The combination of a known product '608 ready for improvement with a known technique '021 and '589 is within the purview of the skilled artisan and would yield predictable results.

Claims 1-2, 5, 8-10, 15-22, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0348683 ('683) and WO 00/18447 in view of Pharmaceutical Industry Info (2002) and further in view of US 5,118,021 ('021) and US 4,905,589 ('589).

- '683 discloses an immediate releasing multi-layered tablet containing two active ingredient layers separated by a non-active ingredient layer (abstract, claim 1, Examples).
- '683 does not teach the same active in the active containing layers, scoring/marking/indicia or the greater height of the inactive layer.
- '447 is taught above and teaches the same active in the same amount with the same dissolution, that is scored or marked and that the inactive layer is greater in height wherein the immediate release compartment is 3/16 diameter round whereas the scored compartment is 5/16x3/4 (abstract, pg. 1 lines 8-10; pg. 3, lines 1-5; Fig. 1; pg. 9, Example) (meeting the limitations of claim 1-2, 5, 8-10, 17, 19-20 and 22).
- '683 and '447 do not teach printed indicia.
- '021 discloses that dosage forms, such as tablets, can be marked or scored for splitting and that reasons for reasons for splitting tablets include difficulty of

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swallowing tablets in whole form and dosage in standard tablet is greater than required (column 1, lines 11-44). '589 discloses that an ink-jet apparatus for marking tablets with appropriate indicia (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '683 and '447 with '021 or '589. A skilled artisan would know how to substitute the drugs of '683 in order to obtain a single drug composition of '447 with predictable results. Such a simple substitution of one drug layer for another is within the purview of the skilled artisan and would yield predictable results. A skilled artisan desiring to make the known product (ie multilayered tablet) of '683 ready for improvement, with the known technique of formulating a product which contains a mark/score/indicia of '447, '021 and '589 with predictable results. The combination of a known product '608 ready for improvement with a known technique '447, '021 and '589 is within the purview of the skilled artisan and would yield predictable results.

### ***Response to Arguments***

Applicant's arguments with respect to the instant claims have been considered but are moot in view of the new grounds of rejection necessitated by applicants' amendments.

### ***Conclusions***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bethany Barham/  
Art Unit 1615

/S. TRAN/  
Primary Examiner, Art Unit 1615